

### **REMARKS/ARGUMENTS**

The Examiner is thanked for her continuing attention to this application and indication of an allowable claim. As to the rejected claims, Applicant respectfully traverses the rejections. The bases for this traversal are discussed below. Applicant has addressed the Examiner's prior art rejections in the order in which they appear in the Office Action.

#### **35 U.S.C. § 112**

Claims 1-28 and 38-39 are objected to because of use of the term out-of-plane microneedles. Applicant respectfully traverses and requests further clarification. The term "out-of-plane" is used throughout the specification and would be well understood to anyone of skill in the art having benefit of the teachings of the application.

#### **35 U.S.C. § 102(e), Claim 8**

Claim 8 stands rejected under 35 U.S.C. § 102(e) as unpatentable over Gonnelli, US Published Application 20030134158. Applicant traverses. The invention of claim 8 is specifically directed to glucose monitoring using a dialysis membrane remaining outside the skin. In particular, the invention of claim 8 is designed specifically to avoid to characteristics discussed in of Gonnelli: "the collection of biological fluid and/or tissue" (Gonnelli [0032]) and "microneedles...employed to sample blood or tissue" (Gonnelli [0051]).

In contrast, in the present invention "a dialysis membrane separates the interstitial fluid and the dialysis fluid; thus, no interstitial fluid is extracted during operation." ([0036]) Applicant traverses the Examiner's assertion that the dialysis membrane is merely a factor of intended use. It is a key element of the claim and enables the declared use, which is continuous glucose monitoring. Nothing in Gonnelli discusses or suggests using a dialysis membrane with a microneedle array or using a microneedle array for continuous monitoring.

#### **35 U.S.C. § 102(a); Claim 38**

Claim 38 stands rejected under 35 U.S.C. § 102(a) as unpatentable over Park. Applicant traverses. Applicant has reviewed Park and the paragraphs cited by the Examiner. Park nowhere suggests or discusses "applying high pressure to a small local surface region

through said microneedles to cause rupture of the cell matrix to open a connection between fluids inside a needle lumen and bodily fluids underneath the broken skin layer” In one of the cited paragraphs [0048], Park discusses “The inner surface of the bore of hollow microneedles can be made rough to enhance cell membrane disruption for those applications in which cell disruption is useful.” Applicant contends that this has no relation to the invention as claimed in claim 38, which describes applying high pressure through a microneedle lumen to make a connection between a needle lumen and a broken skin layer. As an example of claim 38, Applicant invites the Examiner to review the examples shown in Fig. 12 and Fig. 13.

**35 U.S.C. § 103; Claims 1-4, 6, 7, and 39**

Claims 1-4, 6, 7, and 39 stand rejected as being unpatentable over Gonnelli in view of Sage.

As the examiner has recognized, Gonnelli does not teach using a micro-needle array with an external dialysis membrane as taught by the Applicant. The Examiner relies on a combination with Sage to supply the missing elements.

Sage, however, takes a different approach to dialysis. Rather than using a needle array, in Sage a single needle is inserted. This needle is substantially more 10 millimeters in length. Sage, in Fig. 3 shows a layer 12 that is positioned about midway down inside the needle lumen. This membrane is placed within the body during needle insertion.

Applicant objects to the combination on two grounds. First, other than Applicant’s specification, the Examiner has cited no suggestion to combine the references in the prior art. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. In re Geiger 2 USPQ2d 1276 (CAFC 1987); In re Fine 5 USPQ2d 1596 (CAFC 1988). The mere fact that references can be combined does not render the resultant combination obvious unless *the prior art* also suggests the desirability of the combination. In re Fritch 23 USPQ2d 1780 (CAFC 1992).

Furthermore, Sage teaches away from the claimed invention in that Sage discusses a solution for microdialysis that uses an in the body dialysis membrane and a single microdialysis needle that is long enough to contain the dialysis membrane within it.

Applicants invention, by contrast, uses multiple shorter needles, with a dialysis membrane outside the body.

**35 U.S.C. § 103; Claim 5**

Each of the remaining rejections under 35 U.S.C. § 103 rely on the combination of Gonnelli and Sage, which Applicants have overcome above. The Examiner does not argue that any of the additionally cited references show the elements alleged for Gonnelli and Sage above and does not argue that any of the further cited reference provide evidence of motivation to combine the references. Applicant therefore applies the arguments above to these outstanding rejections.

Based on the above remarks, Applicant believes that all outstanding rejections are overcome.

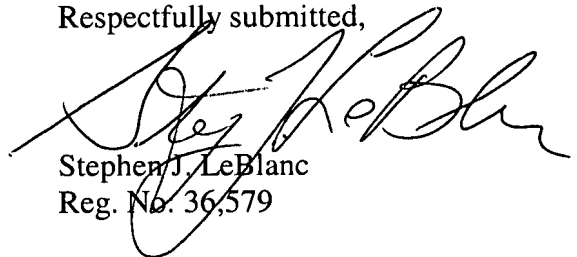
Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3508.

If after consideration of the above response, the Examiner does not find that all pending claims are in condition for allowance, **applicant hereby requests a telephone interview with the Examiner. Please contact the undersigned at (510) 769-3508.**

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Respectfully submitted,



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